GASTROENTEROLOGY RESEARCH NEWS

MEET THE TEAM

The BCCH IBD Research Program is focused on facilitating clinical and observational research studies focused on pediatric Inflammatory Bowel Disease with the goal of improving treatment, diagnosis and characterization of IBD. Our team consists of:

- **Principal Investigators**
  Dr. Kevan Jacobson and Dr. Sally Lawrence
- **Research Coordinators**
  Olga Radivojevic and Zahra Shire
- **UBC Co-op Students**
  Loujain Bilal and Gabriella Guerra

BC Children's Hospital Research Institute

ACTIVE STUDIES

OVATION

PFIZER

Investigational Product: Tofacitinib (Xeljanz)

This study aims to determine if tofacitinib is effective and safe in inducing remission in children with moderate to severe UC who have shown an inadequate response or intolerance to at least one of the following prior therapies: oral IV corticosteroids, AZA or 6-MP, or TNF inhibitors or anti-integrin therapy.

OVATION A3921210

Eligibility:

- Patients aged 6 to <18 years old with moderately to severely active UC with a baseline PUCAI of ≥35
- Clinical diagnosis of UC for at least 12 weeks prior to baseline without a history of dysplasia or colon cancer

TRANSITION TRIAL (PACE)

CROHN'S AND COLITIS CANADA

Intervention: Transition program

This unblinded randomized controlled clinical trial aims to evaluate the clinical and implementation efficacy of an intervention to improve the transition from pediatric to adult care in adolescents and young adults with IBD. The intervention will consist of 4 core components: individualized needs assessment, skill-building, education, and a transition navigator facilitator (nurse practitioner or social worker).

PACE

Crohn's and Colitis Canada
Crohn et Colite Canada

Eligibility:

- Patients with IBD aged 16 to 17.5 years old
- Functional (grade 8 level) English speaking/reading ability
- Intend to reside in Canada after they transition to adult care
- Access to a smart phone

AMBITION-CD

CIDsCaNN and CHILD Foundation

Observational Study

The multi-center Canadian Children IBD Network (CIDsCaNN) brings together investigators across Canada to understand why IBD affects so many Canadian children. We will study children at the time of IBD diagnosis, exploring environmental and exposures; obtaining blood for assessment of genetic risk; and stool for assessment of microorganisms that might be important in the development of IBD. With this prospective cohort study, the goal is to compare outcomes of CD patients with ustekinumab versus anti-TNF as first biologic.

Eligibility:

- CD patients <17 years old who are anticipated to initiate anti-TNF or ustekinumab as treatment
- The duration of CD diagnosis should be ~<18 months
- Perianal disease is NOT the primary or co-primary indication for biologic

STUDIES IN ANALYSIS

COVID-19 VACCINE STUDY

BCCH IBD Research Program

Observational Study

The aim of this study is to determine how pediatric patients with IBD on therapies including infliximab, adalimumab, vedolizumab, and ustekinumab, respond to the SARS-CoV-2 vaccine. This study specifically investigates the effect of immunosuppressants on antibody and virus-specific memory T cell responses at baseline, 28 days, 3-, 6- and 12-months post vaccination.

Preliminary Results:

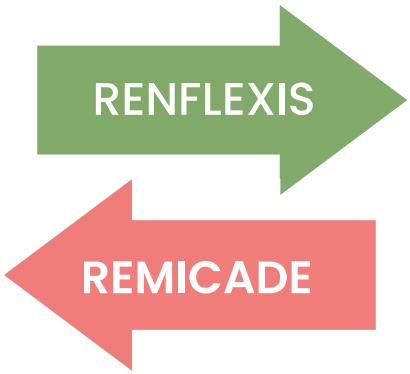
- PIBD patients on maintenance IFX monotherapy had comparable spike and RBD antibody concentrations with uninfected healthy adults 28 days after first SARS-CoV-2 vaccine dose.
- PIBD patients on IFX in combination with MTX or AZA had significantly lower spike and RBD antibody concentrations compared to healthy controls.
- Preliminary findings are discussed further here.

DENT

BCCH IBD Research Program

Observational Study

BC PharmaCare mandated the switch from Remicade to Renflexis in 2020. DENT is a prospective longitudinal observational study that aims to determine the proportion of patients remaining on Renflexis 12 and 24 months after switching and evaluate whether there is a significant difference between IFX trough levels and/or anti-drug antibodies. The secondary aims are to determine whether the proportion of patients in clinical and/or biochemical remission and the proportion of adverse events are similar before and after switching.



Preliminary Results:

- Safe strategy

STUDIES ON THE HORIZON

KEPLER AND WEBB STUDIES

Takeda Pharmaceuticals

Investigational Product: Vedolizumab

The Kepler and Webb studies aim to find out if intravenously-administered vedolizumab is effective and safe in children with **moderate to severe UC** and **moderate to severe CD**, respectively, who have not responded to conventional therapy. Participants will take part in a screening period followed by a 14-week open-label induction period with vedolizumab IV administration. Those who qualify as responders will enter the 40-week 2-dose arm, randomized, double-blind maintenance period with high or low-dose vedolizumab IV q8w.

Eligibility:

- 2-17 year-old patients with moderately to severely active UC (Kepler Study) or moderately to severely active CD (Webb Study)
- Failed or lost response to treatment with at least 1 of the following agents: corticosteroids, immunomodulators, and/or TNF-α antagonist therapy.
  - Includes patients dependent on corticosteroids or exclusive or partial enteral nutrition to control symptoms

MACARONI-23

Eli Lilly and Janssen

Investigational Products: Guselkumab and Mirikizumab

This is a Phase 3 multicenter, randomized, 2-arm, intervention platform program to investigate the efficacy, safety, and PK of 2 different IL-23 inhibitors in pediatric CD. This study will assess the induction and maintenance efficacy of 2 different IL-23 inhibitors (guselkumab [Janssen] or mirikizumab [Eli Lilly]). Participants will be randomized to either the Janssen or Lilly intervention cohort.

Eligibility:

- 2-17 year-old patients with moderately to severely active CD (PCDAI > 30)
- Inadequate response/loss of response, or are intolerant to non-biologic therapy for CD and/or those who failed biologic and/or advanced therapy for CD (eg. biologic/JAK inhibitor-failed)

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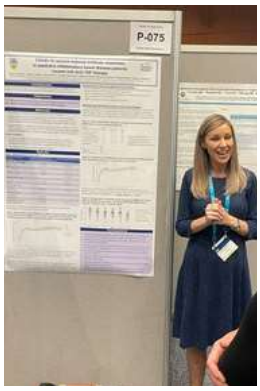
RESEARCH SPOTLIGHT

PEDIATRIC INFLAMMATORY BOWEL DISEASE CONGRESS 2022

Edinburgh, Scotland



Posters of Distinction

Sally Lawrence - COVID-19 vaccine-induced antibody responses in pediatric inflammatory bowel disease patients treated with anti-TNF therapy.

Matthew Smyth - Symptom self-reporting in Pediatric IBD: the feasibility of use for disease activity monitoring and unique pediatric considerations.

Adi Ein Dor - Pediatric inflammatory bowel disease patients with Clostridioides difficile infection have a disrupted gastrointestinal microbiome and more severe disease outcome